K101118
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510(k) Summary

1. Submitter's Name and Address

DEC 15 2010

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Nottinghamshire. NG17 7JZ

Contact Person: Toni Miller PhD
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Date Prepared 26 November 2010

2. Device Name

Trade Name: **Activon Tulle**

Common: Dressing, Wound

Classification Name: Dressing, Wound

Regulatory Class: Unclassified

Product Code: FRO

3. Predicate Devices

Activon Tulle is substantially equivalent to Derma Sciences Medihoney Dressings With Active Manuka Honey -K081584.

4. Device Description

Activon Tulle is a sterile wound care dressing for use in moist wound management. **Activon Tulle** is offered as 2x2 inch and 4x4 inch non-adherent knitted viscose primary dressing impregnated with 100% Manuka honey for effective wound treatment.

5. Statement of Intended Use

Activon Tulle for Over-the-Counter is intended for the management of normal skin and minor wounds, ulcerations and burns, abraded skin, and irritated areas. Under the

supervision of a health care professional, **Activon Tulle** may be used for the management of diabetic foot and leg ulcers, leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology), pressure ulcers/sores (partial and full thickness) , 1st and 2nd degree partial thickness burns, grafted and donor sites, and traumatic and surgical wounds.

6. Technological Characteristics and Substantial Equivalence

Activon Tulle is essentially and substantially equivalent to the predicate devices in its use of Manuka Honey for moist wound management. Both **Medihoney Active APIMED Primary Dressing with Active Manuka Honey** and **Activon Tulle** are offered as tulle dressings in the same sizes; sterilized by gamma radiation; and both are offered without adhesive backing. The technological characteristics are also substantially equivalent and both are suitable for use on pressure sores, leg ulcers, superficial wounds and abrasions, 1st and 2nd degree partial thickness burns and post operative wounds. The difference between them is that **Activon Tulle** is 100% active Manuka honey and does not use calcium alginate that is part of the predicate device.

7. Assessment of Performance Data and Safety

Biocompatibility testing (cytotoxicity, sensitization and irritation) performed with **Activon Tulle** demonstrates that the dressing is safe for its intended use. The performed testing was conducted according to ISO guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Calidad Solutions, Inc.
% LEC Associates, LLC
Toni Miller, PhD
26 Chestnut Ridge Road #12
Montvale, New Jersey 07645

Re: K101118
Trade/Device Name: ActivonTulle®
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 28, 2010
Received: November 30, 2010

DEC 15 2010

Dear Dr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K101118

Indications for Use Statement

Device Name: **Activon Tulle®**

DEC 15 2010

Indications for use:

OTC: For minor wounds, ulcerations and burns, abraded skin, and irritated areas.

Professional: Intended in the management of:

- diabetic foot ulcers;
- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology);
- pressure ulcers/sores (partial and full thickness);
- 1st and 2nd degree partial thickness burns;
- grafted and donor sites and traumatic and surgical wounds.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) And/Or Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEAS DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K101118

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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